

REMARKS

Claims 34; 35-57; 58-60; 61-62; and 63 are pending in the application with Claims 1-33 being previously cancelled. No claims are allowed. Applicants respectfully request favorable reconsideration for the reasons below.

Amendments to the Claims

Independent Claim 58 is amended to recite (iii) *stirring the reaction mixture at a temperature of about 20-90° C.* Support for this amendment may be found, inter alia, on page 8, line 6 of the application as filed.

Independent Claim 61 is amended to recite (iii) *stirring the reaction mixture at about room temperature.* Support for this amendment may be found, inter alia, on page 8, line 26 of the application as filed.

Applicants respectfully submit that no new matter is added.

35 U.S.C. §112 Rejections

Claims 58-63 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps. The Office states that the omitted step is the step of stirring at a specific temperature.

Applicants have amended claims 58 and 61 to recite the requested *stirring* temperatures and believe the Office's concerns have been addressed for these claims and their dependents. Applicants have made the amendments without disclaimer in an effort to advance prosecution.

Regarding Independent Claim 63, however, Applicants respectfully disagree with the Office's rejection and request favorable reconsideration of the claim for at least the reasons below. MPEP 2164.08(c) provides (in part):

In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed

critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

As set forth in the MPEP, broad language in the disclosure that omits an allegedly critical feature, rebuts an argument of criticality. Applicants respectfully direct the Office to page 9, lines 4-15 discussing an embodiment of the present invention. As seen in this embodiment, there is no discussion of *stirring*. For at least this reason, Applicants respectfully request favorable reconsideration of independent Claim 63.

35 U.S.C. §102 Rejections

(1) Independent Claim 34 is rejected under 35 U.S.C. §102 as being inherently anticipated by Lohray *et al.* (WO 97/41067; “Lohray”). Specifically, the Office contends that Lohray discloses a potassium salt having a melting point of 302° C. Applicants respectfully direct the Office’s attention to page 6, line 15 of the application as filed, providing that Form (the subject of claim 34) has DSC endotherms at 296.24° C and 307.64° C. For at least this reason, Applicants respectfully submit that Lohray fails to disclose the claimed crystalline Form and, thus, cannot inherently anticipate the recited limitations of the claimed invention. Applicants request favorable reconsideration of the instant rejection.

(2) Claims 35-57 were rejected under 35 U.S.C. §102 as being inherently anticipated by Chebiyyam *et al.* (WO 00/15638; “Chebiyyam”). Specifically, the Office contends that Chebiyyam’s Example 39 “is presumed to be Form-I because the process in Example 39...is similar to Example 2 of the instant disclosure, which produces Form-I” (emphasis added). Chebiyyam’s Example 39 is provided below:

Example-39

Preparation of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt

5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione obtained by following a procedure described in any of Examples 29-38 (100 g, 0.25 M) was dissolved in 1 L of xylene : MeOH (1 : 1) mixture at 80-90 °C, treated with decolourising carbon (20 g) and filtered. To the filtrate was added potassium hydroxide solution (15.6 g of potassium hydroxide dissolved in 200 ml of methanol) slowly over a period of 5-10 min. at 60-70 °C. Stirring was continued at ambient temperature for a period of 1 h. The solid obtained was filtered, washed with methanol (300 ml) and dried at 120 °C for 1 h to yield 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt as an off-white solid (98 g, Y=89%, P=99.5%).

Applicants respectfully submit that “similarity” between a reference and a claimed invention is insufficient to establish anticipation. Applicants believe it is well established that “[a]nticipation requires the presence in a single prior art reference disclosure of every element of the claimed invention.” *Great Northern Corp. v. Davis Core & Pad. Co., Inc.*, 228 U.S.P.Q. 356, 358 (Fed. Cir. 1986). For at least this reason, Applicants respectfully request favorable reconsideration of the instant anticipation rejection.

Further, it is well settled that “if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public.” *In re Hoeksema*, 158 USPQ 596, 601 (CCPA 1968). Applicants respectfully submit that because Chebiyyam does not anticipate or suggest the process of making Form-I, Chebiyyam cannot be presumed to anticipate the claimed crystalline structure of Form-I.

For example, Chebiyyam’s Example 39 fails to disclose or suggest, at a minimum, applicants’ specific salt addition of Example 2 and applicants’ specific drying step of Example 2. For at least either of these reasons, Applicants respectfully submit that it cannot be legally

concluded that Form-I was in the public's possession, and thus cannot be concluded that Chebiyyam inherently anticipates all of the numerous limitations recited by Claims 35-57. For at least these reasons, Applicants respectfully request favorable reconsideration of the instant rejections.

Further, Applicants would like to note that Chebiyyam's Example 39 fails to disclose or suggest the steps of Claims 58, 61 or 63. For at least these reasons, Applicants respectfully request favorable reconsideration of the instant claims.

Conclusion

Applicants believe that by this amendment, the case is placed in condition for allowance and such action is respectfully requested. If, however, any issues remain unresolved, Applicants' representative would welcome the opportunity for a telephone interview to expedite allowance and issue.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'R. Kody Jones'.

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